

**INFORMATION DISCLOSURE
STATEMENT
PTO-1449**

ATTY. DOCKET NO.

0047.10

SERIAL NO.

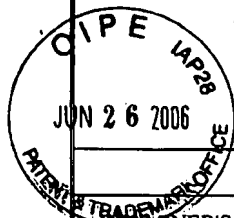
10/601,127

APPLICANT Schuler, et al.

FILING DATE June 19, 2003

GROUP ART UNIT: 3761

Page 1 of 7



U.S. PATENT DOCUMENTS

EXAMINER'S INITIALS	PATENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE
/DE/	2,587,215	02/1952	Priestly			
	3,788,310	01/1974	Fleischmann			
	3,837,341	09/1974	Bell			
	4,086,918	05/1978	Russo			
	4,106,503	08/1978	Rosenthal, et al.			
	4,114,608	09/1978	Russo			
	4,170,228	10/1979	Elson, et al.			
	4,259,951	04/1981	Chernack, et al.			
	4,274,404	06/1981	Molzan, et al.			
	4,284,083	08/1981	Lester			
	4,338,931	07/1982	Cavazza			
	4,391,283	07/1983	Sharpless, et al.			
	4,442,856	04/1984	Betz			
	4,444,202	04/1984	Rubin, et al.			
	4,484,577	11/1984	Sackner, et al.			
	4,495,944	01/1985	Brisson, et al.			
	4,533,137	08/1985	Sonne			
	4,558,710	12/1985	Eichler			
	4,592,348	06/1986	Waters, et al.			
	4,627,432	12/1986	Newell, et al.			
	4,677,975	07/1987	Edgar, et al.			
	4,778,054	10/1988	Newell, et al.			
	4,811,731	03/1989	Newell, et al.			
	4,907,583	03/1990	Wetterlin, et al.			
	4,926,852	05/1990	Zoltan, et al.			
	4,955,371	09/1990	Zamba, et al.			
	4,991,745	02/1991	Brown	222	212	
✓	5,027,806	07/1991	Zoltan, et al.			

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

INFORMATION DISCLOSURE STATEMENT PTO-1449 <u>Page 2 of 7</u>			ATTY. DOCKET NO. 0047.10		SERIAL NO. 10/601,127	
			APPLICANT Schuler, et al.			
			FILING DATE June 19, 2003		GROUP ART UNIT: 3761	
U.S. PATENT DOCUMENTS						
/DE/	5,033,655	07/1991	Brown	222 .	212	
	5,040,527	08/1991	Larson, et al.			
	5,042,467	08/1991	Foley	128	200.23	
	5,042,472	08/1991	Bunin			
	5,069,204	12/1991	Smith, et al.			
	5,167,506	12/1992	Kilis, et al.			
	5,184,641	02/1993	Kuhn			
	5,201,308	04/1993	Newhouse			
	5,213,236	05/1993	Brown, et al.	222	185	
	5,284,133	02/1994	Burns, et al.			
	5,301,666	04/1994	Lerk, et al.			
	5,320,094	06/1994	Laube, et al.			
	5,333,106	07/1994	Lanpher, et al.			
	5,339,995	08/1994	Brown, et al.	222	185	
	5,364,838	11/1994	Rubsamen, et al.			
	5,377,877	01/1995	Brown, et al.	222	105	
	5,385,140	01/1995	Smith			
	5,408,994	04/1995	Wass, et al.			
	5,409,144	04/1995	Brown, et al.	222	185	
	5,419,315	05/1995	Rubsamen			
	5,435,301	07/1995	Herold			
	5,437,271	08/1995	Hodson, et al.			
	5,439,143	08/1995	Brown, et al.	222	185	
	5,447,150	09/1995	Bacon			
	5,447,151	09/1995	Bruna, et al.			
	5,458,135	10/1995	Patton, et al.	128	200.14	
	5,483,954	01/1996	Mecikalski			
	5,497,944	03/1996	Weston, et al.	128	200.14	
✓	5,509,404	04/1996	Lloyd, et al.			

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

INFORMATION DISCLOSURE STATEMENT PTO-1449 <u>Page 3 of 7</u>			ATTY. DOCKET NO. 0047.10		SERIAL NO. 10/601,127	
			APPLICANT Schuler, et al.			
			FILING DATE June 19, 2003		GROUP ART UNIT: 3761	
U.S. PATENT DOCUMENTS						
/DE/	5,513,630	05/1996	Century			
	5,522,380	06/1996	Dwork	128	200.23	
	5,529,059	06/1996	Armstrong, et al.			
	5,533,505	07/1996	Kallstrand			
	5,542,412	08/1996	Century			
	5,558,085	09/1996	Rubsamen, et al.			
	5,568,807	10/1996	Mecikalski	128	203.21	
	5,586,550	12/1996	Ivri, et al.			
	5,617,845	04/1997	Poss, et al.			
	5,622,166	04/1997	Eisele, et al.	128	203.12	
	5,653,223	08/1997	Pruitt	128	200.21	
	5,654,007	08/1997	Johnson, et al.	424	489	
	5,655,520	08/1997	Howe, et al.	128	203.12	
	5,672,581	09/1997	Rubsamen			
	5,692,492	12/1997	Bruna, et al.			
	5,692,496	12/1997	Casper, et al.			
	5,692,498	12/1997	Lurie, et al.	128	205.24	
	5,699,789	12/1997	Hendricks			
	5,724,959	03/1998	McAughey, et al.			
	5,727,546	03/1998	Clarke, et al.			
	5,740,794	04/1998	Smith, et al.	128	203.15	
	5,752,505	05/1998	Ohki, et al.	128	203.15	
	5,775,320	07/1998	Patton, et al.	128	200.14	
	5,785,049	07/1998	Smith, et al.	128	203.15	
	5,813,401	09/1998	Radcliff, et al.			
	5,823,183	10/1998	Casper, et al.			
	5,826,571	10/1998	Casper, et al.			
	5,826,633	10/1998	Parks, et al.	141	489	
✓	5,855,202	01/1999	Andrade			

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

INFORMATION DISCLOSURE STATEMENT PTO-1449 <u>Page 4 of 7</u>			ATTY. DOCKET NO. 0047.10		SERIAL NO. 10/601,127		
			APPLICANT Schuler, et al.				
			FILING DATE June 19, 2003		GROUP ART UNIT: 3761		
U.S. PATENT DOCUMENTS							
/DE/	5,873,358	02/1999	Gonda, et al.				
	5,875,776	03/1999	Vaghefi, et al.				
	5,881,719	03/1999	Gottenauer, et al.	128	203.15		
	5,884,620	03/1999	Gonda, et al.				
	5,896,853	04/1999	Howlett				
	5,901,703	05/1999	Ohki, et al.	128	200.14		
	5,921,237	07/1999	Eisele				
	5,922,354	07/1999	Johnson, et al.	424	489		
	5,941,240	08/1999	Gonda, et al.				
	5,975,076	11/1999	Yianneskis				
	5,983,893	11/1999	Wetterlin				
	5,988,163	11/1999	Casper				
	5,993,421	11/1999	Kriesel				
	6,006,747	12/1999	Eisele				
	6,012,454	01/2000	Hodson, et al.				
	6,029,661	02/2000	Whaley, et al.				
	6,029,663	02/2000	Eisele, et al.	128	203.21		
	6,055,979	05/2000	Fuchs				
	6,055,980	05/2000	Mecikalski				
	6,062,219	05/2000	Lurie, et al.				
	6,065,472	05/2000	Anderson, et al.	128	203.21		
	6,070,573	06/2000	Howe, et al				
	6,076,523	06/2000	Jones, et a.				
	6,085,753	07/2000	Gonda, et al.				
	6,089,228	07/2000	Smith, et al.	128	203.15		
	6,095,134	08/2000	Sievers, et al.				
	6,102,036	08/2000	Slutsky, et al.				
	6,105,574	08/2000	Jahnsson				
	6,109,261	08/2000	Clarke, et al.				
↓	6,116,237	09/2000	Schultz, et al.				

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

INFORMATION DISCLOSURE STATEMENT PTO-1449 <u>Page 5 of 7</u>			ATTY. DOCKET NO. 0047.10		SERIAL NO. 10/601,127			
			APPLICANT Schuler, et al.					
			FILING DATE June 19, 2003		GROUP ART UNIT: 3761			
U.S. PATENT DOCUMENTS								
/DE/	6,116,238	09/2000	Jackson, et al.	128	203.15			
↓	6,116,239	09/2000	Volgyesi					
	6,138,673	10/2000	Shepard	128	203.15			
	6,142,146	11/2000	Abrams, et al.					
	6,161,524	11/1992	Evans					
	6,176,237	01/2001	Wunderlich, et al.	128	203.12			
FOREIGN PATENT DOCUMENTS								
EXAMINER'S INITIALS	PATENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION		
						YES	NO	
/DE/	WO 91/14422	10/1991	PCT/US			<input type="checkbox"/>	<input type="checkbox"/>	
↓	WO 96/09085	03/1996	PCT/US			<input type="checkbox"/>	<input type="checkbox"/>	
	WO 96/32149	10/1996	PCT/US			<input type="checkbox"/>	<input type="checkbox"/>	
	WO 98/32479	07/1998	PCT			<input type="checkbox"/>	<input type="checkbox"/>	
	WO 99/46055	09/1999	PCT			<input type="checkbox"/>	<input type="checkbox"/>	
	WO 99/16419	09/1997	US			<input type="checkbox"/>	<input type="checkbox"/>	
	WO 95/24183	02/1995	US			<input type="checkbox"/>	<input type="checkbox"/>	
	WO 99/47196	03/1999	US			<input type="checkbox"/>	<input type="checkbox"/>	
	WO 95/34337	12/1995	PCT			<input type="checkbox"/>	<input type="checkbox"/>	
	WO 97/40819	11/1997	PCT			<input type="checkbox"/>	<input type="checkbox"/>	
	WO 99/27987	06/1999	PCT			<input type="checkbox"/>	<input type="checkbox"/>	
	WO 96/30068	10/1996	PCT			<input type="checkbox"/>	<input type="checkbox"/>	
	WO 00/21594	04/2000	PCT			<input type="checkbox"/>	<input type="checkbox"/>	
	WO 00/01435	01/2000	PCT			<input type="checkbox"/>	<input type="checkbox"/>	
	EP 0808635A2	11/1997	Europe			<input type="checkbox"/>	<input type="checkbox"/>	
	↓	EP 0714314B1	10/1998	Europe			<input type="checkbox"/>	<input type="checkbox"/>

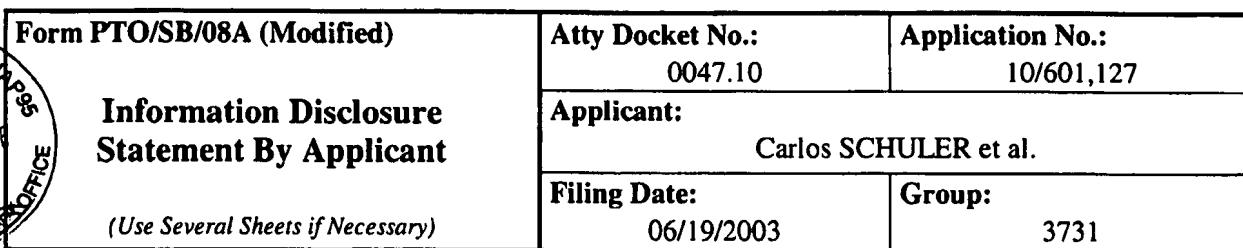
EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

INFORMATION DISCLOSURE STATEMENT PTO-1449 <u>Page 6 of 7</u>			ATTY. DOCKET NO.		SERIAL NO.	
			0047.10		10/601,127	
			APPLICANT Schuler, et al.			
			FILING DATE June 19, 2003		GROUP ART UNIT: 3761	
FOREIGN PATENT DOCUMENTS						
/DE/	EP 0805696B1	03/2000	Europe			<input type="checkbox"/>
↓	HU 212398	06/1996	Boehringer			<input type="checkbox"/>
	HU 219215	03/2001	Merck			<input type="checkbox"/>
	HU 214757	05/1998	Asta			<input type="checkbox"/>
	1,598,053	09/1981	United Kingdom			<input type="checkbox"/>
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)						
/DE/	Nantel, et al., "Flow Targeting System for DPI Clinical Trials," <i>Barrett Medical Aerosol Research Laboratory</i> , pp. 136.					
	Prime, D., et al. "The Flixotide Diskus a new multi powder inhaler-in-vitro evaluation using an inhalation simulator," <i>Glaxo Research and Development</i> , pp 138.					
	Prime, D., et al. "The Flixotide Diskus a new multi powder inhaler-consistency of dose and fine particle mass, protection from moisture," <i>Glaxo Research and Development</i> , pp 137.					
	Robertson, D.L.N., et al., "The influence of (pseudo) polymorphic for,s of lactose on dry power inhaler performance," <i>School of Pharmacy and Pharmacology</i> , pp. 139					
	Barrowcliffe, et al., "The In-Vitro Evaluation of Novel Multi-Dose Dry Power Inhaler," <i>CCL Pharmaceuticals Ltd.</i> , pp. 82-85.					
	Malton, et al., "A Comparison of <i>in vitro</i> drug delivery from two multidose powder inhalation devices," <i>European Journal of Clinical Research</i> , 1995:7; pp. 177-193.					
	Agenda for <i>Asthma Therapy I – Thematic Poster Session May 12, 1996</i> , <i>American Journal of Respiratory Critical Care Medicine</i> , 153(4), April 1996.					
	Malton, et al., "A Comparison of <i>in vitro</i> drug delivery from slabutamol Diskus and terbutaline Turbohaler inhalers," <i>J. Pharm. Med.</i> , (1996) 6, pp. 35-48.					
	Chrystyn, Henry, "The Diskus Inhaler- A Review of its Pharmaceutical and Clinical Performance," <i>Clin. Drug Invest.</i> , 18(4):pp. 287-296 (1999).					
	Newhouse, et al., "Clickhaler (a Novel Dry Powder Inhaler) Provides similar Bronchodilatation to Pressurized Metered-Dose Inhaler, Even at Low Flow Rates," <i>CHEST</i> 115(4):pp. 952-956: April 1999.					
	Clark, "Effect of powder inhaler resistance upon inspiratory profiles in health & disease," <i>Respirator Drug Delivery IV</i> , 1994.					
	Clark, "The relationship between powder inhaler resistance and peak inspriatry conditions in healthy volunteers – implications for in vitro testing," <i>Journal of Aerosol Science</i> , 1993.					
	"Characteristics of an active multiple dose dry powder inhaler," <i>Dura RDD</i> , 1994.					
↓	Dolovich, "Physical principles underlying aerosol therapy," <i>Journal of Aerosol Medicine</i> , 1989.					

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

INFORMATION DISCLOSURE STATEMENT PTO-1449 <u>Page 7 of 7</u>	ATTY. DOCKET NO. 0047.10	SERIAL NO. 10/601,127
	APPLICANT Schuler, et al.	
	FILING DATE June 19, 2003	GROUP ART UNIT: 3761
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
/DE/	Elliott, et al., "Parental absorption of insulin from the lung in diabetic children," <i>Aust. Paediatric Journal</i> , 23, pp. 293-297 (1987).	
	Lawford, et al., "Pressurized Aerosol Inhaler Technique: How Important are Inhalation from Residual Volume, Inspiratory Flow Rate and the Time Interval Between Puffs?", <i>Br. J. Dist. Chest</i> , 77, pp. 276-281 (1983).	
/DE/	Ross, et al., "Effect of Inhalation Flow Rate on the Dosing Characteristics of Dry Powder Inhaler (DPI) and Metered Dose Inhaler (MDI) Products," <i>Journal of Aerosol Medicine</i> , Vol. 9, No. 2., pp. 215-226 (1996).	
	Hill, "Characteristics of an Active, Multiple Dose Dry Powder Inhaler," <i>Respiratory Drug Delivery IV</i> , pp. 109-116 (1994).	
/DE/	Conway, et al., "Comparison of peak Pressure Drops Through Powder Inhalers During Inspiration at Maximum Flow Rate" Abstract from <i>American Journal of Respiratory and Critical Care Medicine</i> , Vol. 153, No. 4, A59, (April 1996).	
EXAMINER	/Darwin Erez/	DATE CONSIDERED 04/19/2007

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[illegible]

04/19/2007

Pg. 1 of 1